

### **Detailed Action**

This detailed action is in regards to United States Patent Application 10/519431 filed on September 6, 2005 and is a first action based on the merits of the application.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 9, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito (EP 0513789 A2).

Regarding **claim 1**, Ito discloses an apparatus comprising: a distributed inlet (sampling cell 1, see Figure 2) for collecting and mixing wound fluids from a plurality of locations in a wound to provide a wound fluid mixture; and a sensing or indicating device in fluid communication with said distributed inlet (sensing element 14, see Figure 2 and Column 6, Lines 33-38) for detecting the presence of a wound fluid marker in the wound fluid mixture.

Regarding **claim 4**, Ito discloses the apparatus of claim 1 as set forth above, further comprising a device for applying suction to the distributed inlet (suction pump 7, see Figure 2).

Regarding **claim 5**, Ito discloses the apparatus of claim 1 as set forth above, further comprising a liquid supply port to supply a washing liquid to the wound (Figure 2 shows the device comprising a liquid supply port which supplies a liquid 16 to the skin surface 3, see also Column 6, Lines 38-48).

Regarding **claim 7**, Ito discloses the apparatus of claim 1 as set forth above, wherein the sensing or indicating device (14) contains one or more immunological binding partners (a sensor comprising a membrane on which glucose oxidase are

immobilized, see Column 5 Lines 32-37) to bind one or more marker molecules present in the wound fluid.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito (EP 0513789 A2) in view of Kajiwara et al. (US 5,762,640).

Ito teaches the invention as discussed above and further teaches, regarding claim 2, the apparatus according to claim 1 as set forth above, wherein the distributed inlet comprises a spacer, see Figure 2 and wherein the distributed inlet is a sheet or plate, see Figure 2.

Ito fails to disclose the apparatus wherein the inlet is selected from the group consisting of a plurality of spaced apart capillary tubes, or a body of absorbent material, or a combination thereof and fails to disclose the apparatus wherein the inlet has an area of at least 10cm<sup>2</sup>.

Kajiwara teaches an apparatus for collecting fluid wherein the distributed inlet (disk 1, see Figures 2a and 2b) is selected from a plurality of spaced apart capillary tubes (guide grooves 4 and holes 2, see Figures 2b, 3 and Column 3, Lines 18-31). Kajiwara teaches an apparatus for collecting fluid wherein the distributed inlet (disk 1, see Figures 2a and 2b) has an area of at least 10cm<sup>2</sup> (30mm diameter, see Column 3, Lines 40-45).

Both Ito and Kajiwara teach fluid collection devices.

Thus, it would have been obvious to a person of ordinary skill at the time of the invention to modify the apparatus disclosed by Ito to include a plurality of spaced apart

capillary tubes as taught by Kajiwara in order to provide capillary action and exclude air from the device thereby improving accuracy, see Kajiwara Column 3, Lines 18-31.

Further regarding the area, all of the elements are known in the prior art and one of ordinary skill in the art could have combined the apparatus disclosed by Ito with the inlet area taught by Kajiwara with no change in their respective functions, and the combination would have yielded the predictable results, an apparatus having an inlet in the form of a sheet or plate having an area of at least 10cm<sup>2</sup>, to one of ordinary skill in the art at the time of the invention. Therefore, it would have been obvious to a person of ordinary skill at the time of the invention to modify the apparatus disclosed by Ito by modifying inlet to have an area of at least 10cm<sup>2</sup> as taught by Kajiwara.

9. Claim 6 rejected under 35 U.S.C. 103(a) as being unpatentable over (EP 0513789 A2) in view of Freitag et al. (US 6,214,629 B1).

Regarding **claim 6**, Ito discloses the apparatus according to claim 1 as set forth above but fails to disclose the device wherein the sensing or indicating device is visible through a side wall of the apparatus, and undergoes a visible change in the presence of said wound fluid marker. Freitag teaches an apparatus wherein the sensing or indicating device is visible through a side wall of the apparatus (window 41, see Figure 3A), and undergoes a visible change in the presence of said wound fluid marker (generation of a color in the same indicative of the presence of an analyte (see Column 14, Lines 42-48)).

Both Ito and Freitag teach fluid testing devices. Thus, it would have been obvious to a person of ordinary skill at the time of the invention to modify the apparatus disclosed by Ito to by incorporating the indicating device which undergoes a visible change and is visible thought a side wall of the apparatus as taught by Freitag in order to allow the user to view the test results, see Freitag Column 6, Lines 9-14.

10. Claim 8 rejected under 35 U.S.C. 103 (a) as being unpatentable over Ito (EP 0513789 A2) in view of Bentsen et al (US 6,372,958 B1).

Regarding **claim 8**, Ito discloses the apparatus according to claim 1 as set forth above wherein the sensing or indicating device comprises a substrate (membrane) for substances present in the wound fluid, (see Column 4 Lines 55-59 and Column 5, Lines 32-38). Ito fails to disclose the apparatus wherein the substrate is a chemiluminescent chromogenic or fluorogenic substrate for an enzyme present in the wound fluid. Bensten teaches a assay for monitoring biological activity wherein a fluorogenic substrate indicator for the detection of enzymes secreted by bacteria, (see Abstract and Column 2, Lines 49-62).

Both Ito and Bentsen teach assay devices. Thus, it would have been obvious to a person of ordinary skill at the time of the invention to modify the apparatus disclosed by Ito to include a fluorogenic substrate as taught by Bentsen in order to detect the presence of bacteria by detecting the bacterial enzymes, see Bentsen Column 2, Lines 49-62.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ito (EP 0513789 A2) in view of Ferguson et al. WO 02/30478 A2.

Regarding **claim 9**, Ito discloses the apparatus according to claim 1 as set forth above. Ito fails to disclose the apparatus wherein the sensing or indicating device detects one or more molecules selected from the group consisting of: protease enzymes, collagen propeptides, collagen telopeptides and collagen crosslinks. Ferguson teaches an apparatus comprising an indicator for protease enzymes in exudate, see Page 8, Line 30 thru Page 9, Column 5.

Both Ito and Ferguson teach assay devices. Thus, it would have been obvious to a person of ordinary skill at the time of the invention to modify the apparatus disclosed by Ito to include a protease enzyme indicator as taught by Ferguson in order to detect the presence of bacteria, see Ferguson Column 2, Lines 49-62.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ito in view of Te Koppele et al. US 6,127,139.

Regarding **claim 10**, Ito discloses the apparatus according to claim 1 as set forth above, wherein the sensor or indicating device detect a component of exudate. Ito fails to disclose the apparatus wherein the sensing or indicating device detects one or more enzymes selected from the group consisting of matrix metalloproteinases, low molecular weight gelatinase, latent or active elastases and alkaline phosphatase (ALP). Te Koppele teaches a assay device wherein fluorogenic substrates (indicator/sensor) that can be selectively hydrolyzed by matrix metalloproteinase, see Column 1, Lines 8-34.

Both Ito and Te Koppele teach assay devices. Thus, it would have been obvious to a person of ordinary skill at the time of the invention to modify the apparatus disclosed by Ito to include a matrix metalloproteinase indicator as taught by Te Koppele in order to provide an indicator of several conditions including wound healing, see Te Koppele Column 8, Lines 58 – Column 9, Line 7.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. US 6533735 discloses a suction device for detecting infections agents.
- b. US 7037277 B1 fluid collection and sensor device.
- c. US 6372182 B1 fluid collection and analyzing device.
- d. US 2001/0029956 wound treatment device.
- e. JP 10085293 A exudate collection device.
- f. US 5782871 Fluid suction device.
- g. US 5417206 Fluid collection device.
- h. US 2003/0119073 A1 enzyme detection sensor.

### ***Contact Info***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is

(571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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